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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,698	02/08/2002	Dirk Muessig	7163-38	2519
21324	7590	04/12/2005	EXAMINER	
HAHN LOESER & PARKS, LLP			LEUBECKER, JOHN P	
One GOJO Plaza				
Suite 300			ART UNIT	PAPER NUMBER
AKRON, OH 44311-1076			3739	

DATE MAILED: 04/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/072,698	MUESSIG ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	John P. Leubecker	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 24 January 2005.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-8 and 17-47 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-8 and 17-47 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

*Drawings*

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the balloon (claims 17-40) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

*Claim Objections*

2. Claims 1 and 47 are objected to because of the following informalities: phrase "blood vessels, in particular blood vessels" is improper and should be changed to "blood vessels,". Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 6, 18, 22, 26, 30, 34, 38, 42 and 47 are rejected under 35 U.S.C. 102(a) (or 102(e) if foreign priority is perfected) as being anticipated by Stelzer et al. (U.S. Pat. 6,309,345).

Stelzer et al. disclose a catheter sheath (58, Fig. 2), having a distal catheter portion (Fig. 1), an illumination device (3,4), an image recording unit (1,2), an image reproduction unit (col.6, lines 33-38), and an electrode (253,263, Figs. 9 and 10) and electrode line (portion of the electrode extending to the proximal end) integral with the catheter sheath (within node 251 which is on distal catheter portion, note nodes 6,8,10 of Figure 1). The electrode is made of metal (col.11, line 3) and thus inherently would be capable of delivering and receiving an electric signal. Therefore, the electrode (253,263) is “adapted for at least one of: delivering an electrical signal to body tissue adjoining the distal catheter portion and receiving an electrical signal from body tissue adjoining the distal catheter portion”.

As to claim 6, the illumination device (3,4) are fiber optics that are integral with the catheter sheath (Fig. 1). As to claims 18, 22, 26, 30, 34 and 38, note balloon (504, Fig. 14) which, due to its outward expansion, is capable of the claimed intended uses. Also note column 13,

lines 26-40. As to claim 42, note that Stelzer et al. discloses that means for controlling the deflection of the distal end are known (col.6, lines 11-14), states that the sheath accommodates “control cabling” (making them “integral”) for orientation and introduction into the body (col.7, lines 12-14), and refers to a prior art bending mechanism (col.7, lines 14-16) which uses wires extending from the distal end to the proximal end. As to claim 47, all elements of this claim have been mentioned above.

5. Claims 1, 18, 22, 26, 30, 34, 38 and 42 are rejected under 35 U.S.C. 102(b) (or 102(e) if foreign priority is perfected) as being anticipated by Amundson et al. (U.S. Pat. 6,178,346).

Amundson et al. discloses the combination of a “blood endoscope”, which meets the limitations of an illumination device, an image recording unit and a reproduction unit (note numbered paragraph 2 of the previous Office Action, paper number 9, and page 5 of the Examiner’s Amendment, mailed out on November 17, 2004), and a electrode catheter (note col.8, line 35 to col.9, line 21). The endoscope is capable of providing images with a wavelength for which blood has a high transparency (col.6, lines 3-20). By the nature of an electrode catheter, such includes a sheath with an integral electrode (which would inherently include a wire or wires for energizing the electrode).

6. Claims 1-3, 6-8, 42-44 and 47 are rejected under 35 U.S.C. 102(b) (or 102(a) if foreign priority is perfected) as being anticipated by Kranz (EP 1 072 281).

Kranz disclose a catheter sheath (10) and distal catheter portion (12). With reference to the embodiments shown in Figures 6 and 7 (paragraphs [0030]-[0032]), integral optical fibers

(90,92) provide illumination light at wavelengths between 600-650 nm (for which blood is transparent) and an imaging sensor ([0032]) is used to obtain an image (which will also be at the 600-650 nm wavelength). Although no electrode or electrode line is shown in the catheter of Figures 6 and 7, Kranz defines “catheter” as intended to cover electrode lines and ablation catheters ([0001]). By the inherent nature of such catheters, the Kranz catheter would then include an electrode, integral with the catheter sheath and proximate the distal catheter portion, that is capable of delivering and receiving electrical signals to body tissue. The catheter includes a means for controlling the deflection that is integral with the catheter ([0021]).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 2-5,7, 8, 17, 19-21, 23-25, 27-29, 31-33, 35-37, 39-41 and 43-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stelzer et al. in view of Roth (U.S. Pat. 6,079,414).

Stelzer et al. explicitly discloses imaging using a wavelength for which blood has a high transparency (col.6, lines 54-61) but fails to provide any particular wavelengths or wavelength ranges. Thus, one of ordinary skill in the art would naturally and obviously turn to the prior art for such knowledge. Roth, by incorporation by reference (col.18, lines 16-26) of the teachings of

Fantone et al. (U.S. Pat. 4,786,155), teaches employing a light filter (col.18, lines 16-19) to transmit illumination light having wavelengths between 600 nm and 650 nm (Fantone et al., col.4, lines 31-35) and record such wavelengths (col.18, lines 19-21) to provide an image of objects through blood (col.18, lines 21-26). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have, base on the suggestion of Stelzer et al. to “see through blood”, used the filter of Roth to provide the appropriate wavelengths for such function, since such structure and function was known in the art for the same purpose.

9. Claims 4, 5, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kranz in view of Roth.

Although the Examiner takes the position that it is well within the level of ordinary skill in the art to use a band pass filter with a broad band light source to obtain any desired wavelength range (the only other alternative is to use a light source that emits within the desired range), Roth is being cited to evidence that such method of using a filter for producing light within the claimed range for the same purpose has been contemplated in the prior art (col.18, lines 16-26). Since light sources which emit in specific narrow wavelength bands can be expensive, one might be motivated to use a broad band source and filter arrangement to decrease cost.

10. Claims 18-20, 22-24, 26-28, 30-32, 34-36, 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kranz in view of Stelzer et al.

Kranz discloses a catheter intended for intravascular use ([0001]) but fails to disclose a balloon at the distal catheter portion. Stelzer et al. disclose an analogous device and teaches that it would be advantageous during intravascular use to employ a balloon on the catheter for such procedures as deploying stents, grafts, and occluders. It would therefore have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a balloon on the catheter of Kranz for the advantageous reasons taught by Stelzer et al.

11. Claims 17, 21, 25, 29, 33, 37 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kranz in view of Roth and further in view of Stelzer et al.

As set forth immediately above, for the same reasons, it would therefore have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a balloon on the catheter of Kranz for the advantageous reasons taught by Stelzer et al.

#### *Response to Arguments*

12. Applicant's arguments filed January 24, 2005 have been fully considered but they are not persuasive.

#### *Conclusion*

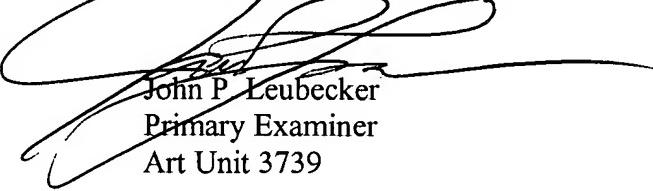
13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kranz et al. (U.S. Pat. 6,547,757)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Leubecker whose telephone number is (571) 272-4769. The examiner can normally be reached on Monday through Friday, 6:00 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



John P. Leubecker  
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jpl